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Patent
Attorney Docket No. 4389

UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Brian E. Dalton	)	
		)	
Application No.:	10/642,976	)	Swiger III, James L.
		)	Patent Examiner
Filed:	August 18, 2003	)	Art Unit 3733
		)	
For:	CERVICAL COMPRESSION PLATE ASSEMBLY	)	
		)	Pittsburgh, Pennsylvania

APPLICANT'S BRIEF ON APPEAL

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Appeal Brief is submitted under Part 41 of Title 35 U.S.C. 134(a) and (b) in accordance with the provisions of 37 C.F.R. 1.191. The required fee of $255.00 for a small entity is submitted herewith in the form of a check made payable to the Director of Patents and Trademarks.

REAL PARTY IN INTEREST

The real party in interest is the inventor Brian E. Dalton.

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A Claims Appendix is attached containing a copy of claims 1 - 18 on appeal, and an Evidence Appendix and a Related Proceeding Appendix are also attached as required by the Rules.

Respectfully submitted,

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RELATED APPEALS AND INTERFERENCES

There are no other prior and pending appeals, interferences or judicial proceedings known to Appellant, the Appellant's legal representative, or Assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF THE CLAIMS

Claims 1 through 18 were originally filed with the application. Claims 1 and 10 are the only independent claims.

In the first Office Action dated June 29, 2006, the Examiner indicated that claims 1 - 18 were pending in the application, and that claims 6, 7 and 14 - 16 were withdrawn from further consideration by the Examiner as being drawn to a non-elected invention, and that claims 9 and 18 contained allowable subject matter. Then in the Office Action dated December 19, 2006, the Examiner withdrew the previous election restriction and the indication of allowability. Accordingly, now claims 1 through 18 are pending in the application, and claims 1 through 18 have been rejected.

Claims 1 through 18 are therefore now the rejected claims being appealed.

STATUS OF AMENDMENTS

A reply, without further amendment to the claims, was submitted in response to the Final Office Action dated September 7, 2007. Accordingly, no amendment was filed subsequent to final rejection.

SUMMARY OF CLAIMED SUBJECT MATTER

a.) Concise explanation of the subject matter defined in each of the independent claims.

Independent claims 1 and 10 are the only independent claims.

Claim 1 is directed to a cervical compression plate assembly which is generally secured to adjacent vertebra and causes the adjacent vertebra to provide continuous compressive loading on bone graph material that is disposed between the vertebral elements after the disc has been removed. This materially assists in the bone grafting process.

Referring to the embodiment of FIGS. 1 and 2, and line 10 of page 13 through line 21 of page 15 of the present specification, a concise explanation of the subject matter defined in independent claim 1 follows.

The cervical compression plate assembly 10 is provided with screw receiving elements 11 and 12 at opposite ends thereof. These screw receiving elements 11 and 12 are configured for engaging bone fixation screws 13 (see FIG. 3) extending from the respective vertebral elements 11 and 12. Means is provided for permitting the distance between screw receiving elements 11 and 12 to be shortened. In the embodiment of FIGS. 1 and 2 this means is provided in the form of dowel pin 16 as confined within slot 17 which limits the relative movement between screw receiving elements 11 and 12. The screw receiving elements 11 and 12 may thus be compressed together towards each other to shorten the distance therebetween. However, when once compressed together, the screw receiving elements 11 and 12 are prevented from thereafter separating. In the embodiment of FIGS. 1 and 2, this is accomplished through the use of a compression spring means 20 provided in the form of a tension wire 21 that has elastic characteristics whereby the tension of the wire will not drop too precipitously. The result is that when the screw receiving elements are secured to adjacent vertebral elements of the body, they provide continuous compressive loading on bone graph material which may be disposed between the vertebral elements to facilitate eventual grafting when bone graph material is substituted between the vertebral elements for the original damaged disc which had been removed.

The compression spring means 20, 21 of FIG. 1 may be substituted with different embodiments thereof such as illustrated in FIGS. 10, 17 and 20.

Regarding independent claim 10, a concise explanation of the subject matter defined in this independent claim follows with reference to a different embodiment shown in FIG. 10, 11 and 12

with further reference to the specification, beginning at line 19 of page 18 and continuing on through to line 2 of page 20.

Mapping claim 10 in this regard, the cervical compression plate assembly 10 includes first and second elongated plates 11 and 12 which are slidably received with respect to each other in their longitudinal direction for adjustably changing the distance between opposite ends 24 and 25 of the plate assembly 10. The opposite ends 24 and 25 of first and second plates 11 and 12 are configured for respective attachment to first and second vertebra of a body with the aid of bone fixation screws 13 (as previously discussed with the embodiment of FIGS. 1, 2 and 3).

A lock assembly is provided for locking the first and second plates 11 and 12 from further relative distraction therebetween. This lock assembly in this embodiment is provided in the form of a ratchet and pawl mechanism 51 which includes a washboard rack 52 provided in upper plate 11 and a flexible pawl 53 secured to lower plate 12. The pawl 53 is provided with an inwardly protruding lip 54 which engages between the ratchet teeth of rack 52. The teeth of rack 52 are so designed whereby the distance between screw receiving elements 11 and 12 may decrease but may not increase as the pawl 53 will slide over the teeth of rack 52 as the upper and lower plates 11, 25 and 12, 24 are compressed toward each other, but will grip back sides of these teeth and prevent any separation thereof.

Finally, a compression spring means 20 is received in the plate assembly 10 and configured for urging opposite ends of the assembly 10 together for thereby providing continuous compressive loading.

In this embodiment compressive spring means 20 is comprised of four coil tension springs 50 that are provided with two springs being housed on each side of the assembly 10 in respective compartments 55 and 56 provided within the assembly 10. Opposite ends of stretch springs 50 are secured to the respective upper and lower plates 11, 25 and 12, 24 with pins 57. The stretch springs 50 can generate approximately two pounds of force under tension and therefore in combination generate approximately eight pounds of force.

In yet another embodiment as seen in FIGS. 13 through 19, and as specifically described in the specification, beginning at line 3 of page 20 through line 7 of page 21, the stretch springs 50 of the previous embodiment may be substituted with compression springs 70, instead of the stretch springs 50, for the spring means 20 here. The springs 70 are wire coiled compression springs.

While at first glance in this embodiment one might believe that the compression springs 70 force the two screw receiving elements 11 and 12 apart, this in fact is not the case. The assembly is configured whereby the compression springs do just the opposite and continuously compress the two elements 11 and 12 together so that they converge toward each other.

b.) Identification of every means plus function.

Next, for each independent claim involved in the appeal and for each dependent claim argued separately, every means, plus function and step plus function, as permitted by 35 U.S.C. 112, sixth paragraph, is identified, and the structure, material, or acts described in the specification as corresponding to each claim function is set forth with reference to the specification by page and line number, and to the drawings, by reference characters.

Referring first to the first means plus function in independent claim 1, defined in claim 1 as "means for permitting the distance between said screw receiving elements at opposite ends to be shortened but preventing said distance from increasing", this first means plus function as recited in independent claim 1 is next described with reference to the different embodiments of the present invention by specific reference to the specification by page and line number and to the drawings. This means plus function will be referred to as the first means plus function of claim 1.

This first means plus function of claim 1 with regard to the embodiment disclosed in FIGS. 1 and 2 is specifically described beginning at line 13, on page 14 of the specification on through line 4 of page 15, of the specification and corresponds to the interrelationship of dowel pin 16 as confined within slot 17 in combination with the compression tension applied to the assembly 10 by tension wire 21 which draws the opposed screw receiving elements 11 and 12 together.

Next, with reference to the embodiment shown in FIGS. 6 through 12, this first means of independent claim 1 is specifically described in the specification, beginning at line 3 of page 19 through line 11 of page 19. This first means in this embodiment corresponds to the ratchet and pawl mechanism 51 which interacts with washboard rack 52 provided on upper plate 25 and the flexible pawl 53 secured to the lower plate 24, in further combination with the inwardly protruding lip 54 of pawl 53 which engages the ratchet teeth of rack 52.

With regard to the embodiment of FIGS. 13 through 19, and also the embodiment of FIGS. 20 through 23, the first means of independent claim 1 is specifically described in the specification, beginning at line 14 of page 20 through line 7 of page 21. This first means, as with the previous embodiment, includes the elements protruding pawl 54 which is combined with ratchet mechanism 51 for engaging the washboard ratchet rack 52 in the same manner as described with respect to the previous embodiment.

The second means plus function of independent claim 1 is the "compression spring means housed in said assembly and configured for continuously urging said screw receiving elements at opposite ends together for thereby providing continuous compression loading on bone graph material disposed between the vertebral elements". This second means plus function of claim 1 is described with reference to the embodiment of FIGS. 1 and 2 in the specification, beginning at line 5 on page 15 through line 21 of page 15. This second means plus function of claim 1 for this first embodiment consists of a combination of the tension wire 21 which may be tightened to increase the tension with ratchet gear 26.

With respect to the second embodiment of FIGS. 6 through 12, this second means of independent claim 1 is specifically described in the specification, in lines 19 of page 18 through line 3 of page 19, and continuing in lines 12 through 18 of page 19. This second means plus function of claim 1 is comprised of coil tension springs 50.

Next, with regard to the embodiments of FIGS. 13 through 19 and 20 through 23, this second means plus function of independent claim 1 is specifically described in the specification, beginning at line 3 of page 20 and continuing through line 10 of page 20, and further continuing beginning with line 19 of page 20 through line 3 of page 21, and further continuing beginning at line 8 of page 21 and continuing through line 10 of page 21. In these embodiments, the second means plus function of independent claim 1are comprised of the compression springs 70 as arranged in combination with the lower end 78 of band 73 and the outward protruding lip 76.

Turning next to independent claim 10, the first means described therein is the "means for permitting the distance between said opposite ends to be shortened".

This first means of independent claim 10 is specifically described in the specification with reference to the embodiment of FIGS. 1 and 2, beginning at line 13 on page 14 and continuing on to line 4 of page 15. This first means plus function in claim 10 in specific is constituted of the two screw receiving elements 11 and 12 at opposite ends of the assembly 10 which are so inter-engaged that they may be slidably engaged whereby the distance between the opposite ends of elements 11 and 12 may be shortened.

This same first means plus function of independent claim 10 is further described with regard to the embodiment of FIGS. 6 through 12, 13 through 19, and FIGS. 20 through 23, in the specification by the same description just previously indicated with regard to the embodiment of FIGS. 1 and 2 since all the embodiments operate the same in this regard in that the inter-engaging screw receiving elements 11 and 12 at opposite ends of the plate assembly 10 may be shortened, and it is specifically indicated in the specification that the latter embodiments of FIGS. 6 through 12, FIGS. 13 through 19, and FIGS. 20 through 23, operate in the same basic manner.

With regard to the second means plus function set forth in independent claim 10, namely the "compression spring means received in said plate assembly and configured for urging said opposite ends together for thereby providing continuous compressive loading", a specific description thereof is provided in the specification with regard to the first embodiment of FIGS. 1 and 2, beginning at line 13 on page 14 and continuing on through line 21 of page 15. This second means plus function for this first embodiment of FIGS. 1 and 2 is comprised of spring wire 21 which is tensioned through ratchet gear 26.

With regard to the embodiment of FIGS. 6 through 12, this second means plus function of independent claim 10 is specifically described in the specification, beginning at line 12 of page 19 and continuing on through line 18 of page 19. In this embodiment this second means plus function is comprised of coil tension springs 50.

Regarding the embodiments of FIGS. 13 through 19 and 20 through 23, this second means plus function of independent claim 10 are described specifically in the specification, beginning at line 3 of page 20 and continuing on through line 3 of page 21. In specific, this second means plus function of independent claim 1 with regard to these embodiments is comprised of compression springs 70 which are so arranged between lower end 78 of band 73 and outwardly protruding lip 76 so as to continuously urge the screw receiving elements 11 and 12 to converge towards each other.

For each dependent claim argued separately, no additional means plus function or step plus function elements exist.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

There are four grounds of rejection presented for review. The first ground is rejection of claims 1 - 2, 5 - 6, 8, 10 - 11, 14 - 15 and 17 under 35 U.S.C. 102(b) as being unpatentable over Beer et al.

The second ground of rejection presented for review is the rejection of claims 1 - 2, 5 - 6, 8, 10 - 11, 14 - 15 and 17 under 35 U.S.C. 102(e) as being anticipated by Sevrain.

The third ground of rejection presented for review is the rejection of claims 3 - 4 and 12 - 13 under 35 U.S.C. 103(a) as being unpatentable over Sevrain in view of Richelsoph et al.

The fourth ground of rejection presented for review is the rejection of claims 7 and 16 under 35 U.S.C. 103(a) as being unpatentable over Sevrain in view of Serbousek et al.

ARGUMENT

Ground (1): The rejection of claims 1 - 2, 5 - 6, 8, 10 - 11, 14 - 15 and 17 as being anticipated by Beer et al.

In specific, in making this rejection, the Examiner states "The device is capable of providing loading on graph material (12) disposed between the vertebral elements." It is respectfully submitted that this statement is totally inaccurate. The Examiner further states that the spring of Beer et al. may be considered a wire under tension.

Beer et al. discloses a prosthesis element that does not, is not intended to and cannot impose loading on a bone graph material interposed between adjacent vertebral elements. To the contrary, the Beer et al. prosthetic device is an artificial prosthetic spring loaded device positioned between adjacent vertebral elements in substitution of the removed disc. It is intended and designed only to absorb compression and provide cushioning between adjacent vertebra in substitution of the removed disc.

The Examiner takes the position that because the springs of the device are securely connected to the upper and lower plates 11a and 11b that therefore the prior art device can function as

Applicant's claimed device. This is impossible. Beer et al. discloses a device that does exactly the opposite to the teachings of Applicant's claimed invention and cushions or pushes or urges the adjacent vertebral elements apart.

It is not possible to maintain that the Beer et al. device is capable of providing loading on graph material disposed between adjacent vertebral elements when in fact there is no such teaching or suggestion, and in fact, the reference teaches the exact opposite and does not even recognize that such compressive loading might even be advantages. In addition, the Beer et al. prosthetic device does not even provide space for inserting a bone graph between his upper and lower plates 11a and 11b or between adjacent vertebra.

Accordingly, the Examiner fails to articulate in an adequate rationale for combining the prior art to attain the claimed invention. The Examiner's attempting to push the guidelines of KSR beyond its intended boundaries.

First of all, there is no evidence or suggestion in the prior art of Applicant's configuration. In fact, the prior art does not even recognize the desirability of providing compressive loading on bone graphs inserted between adjacent vertebra. *See Ex Parte Katoh et al.,* Appeal 20071460, Decided May 29, 2007.

The Examiner has not even provided any evidence that it was conventional in the art to provide such compressive loading on bone graph between adjacent vertebra. In this regard, see *Ex Parte Owlett,* Appeal 20070644, Decided June 20, 2007.

As stated *In Re Kahn,* 441 F. 3d 977,988 (CA Fed. 2006), and cited with approval in KSR, "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness".

In the instant case, it must be concluded that a person of ordinary skill in the art having common sense at the time of the invention would not have reasonably looked to Beer et al., or for that matter any of the other cited references, to solve a problem which was not even recognized by the prior art or the artisan of ordinary skill. Namely, references and the person of ordinary skill in the art did not and have not even recognized that it is even desirable to apply compressive loading to bone implants between adjacent vertebra in order to facilitate grafting. How then could any of these references be considered to obviously disclose the teachings of the present invention, when in fact they were intended to be used in an entirely different manner and for an entirely different purpose. In this regard, see *Ex Parte Rinkevich et al.,* Appeal 20071317, Decided May 29, 2007.

Ground (2): The rejection of claims 1 - 2, 5 - 6, 8, 10 - 11, 14 - 15 and 17 under 35 U.S.C. 102(e) as being anticipated by Sevrain.

In regard to this rejection the Examiner makes the incorrect conclusion that the tension spring (39) of Sevrain is capable of holding the plate in a compressed position and refers to column 5, line 60 - 65 of the reference. However, it is respectfully submitted that the quoted lines do not support the Examiner's position. The reference states that the springs provide a "floating" so that the spring forces always bring it back to its at rest position. Once again, this is merely describing a prosthetic device for providing a cushioning between adjacent vertebra in substitution of the original cushioning of the natural disc which has been removed. Since the device comes to its at rest position, it is impossible for it to be as seen as continuously urging the screw receiving elements at opposite ends together for thereby providing continuous compressive loading on bone graph material disposed between the vertebral elements. There is no such guidance, teaching or suggestion in the reference.

Once again, this prior art of Sevrain does not even recognize that it is even desirable to provide compression loading on a bone graph between adjacent vertebra in order to enhance grafting. Therefore, for the same legal reasons given with regard to the Beer et al. reference, it is Applicant's position that one of ordinary skill in the art, applying common sense, could not have discovered the present invention even by reasonably looking to the prior art cited by the Examiner. The prior art is solving an entirely different problem and does not even recognize the advantages of the apparatus of the present invention.

Ground (3): The rejection of claims 3, 4 and 12, 13 under 35 U.S.C. 103(a) as being unpatentable over Sevrain in view of Richelsoph et al.

The Examiner makes the same rejection based on Sevrain as previously made and therefore the foregoing arguments and legal guidelines also apply in the present instance.

In addition, the Examiner makes the conclusion that Richelsoph et al. discloses a removable spacer (16) preventing the screw-receiving elements from being shortened at opposite ends. This statement is also inaccurate. Obviously, once the bone screws in Richelsoph et al. are set, they are locked and there is no relative movement. In addition, Richelsoph et al. does not disclose, suggest or permit relative movement between opposite ends of his device.

Ground (4): The rejection of claims 7 and 16 as being unpatentable over Sevrain in view of Serbousek et al. under 35 U.S.C. 103(a).

Again, the Examiner applies Sevrain in the same manner as previously applied and makes the misguided and inaccurate statement that Sevrain discloses the claimed invention except for a torque driving device to apply tension to the wire spring. For this element the Examiner turns to Serbousek et al., referring to the torque device (134/128) that causes torque to the spring (85, and see FIG. 5).

A combination of the teachings of these references does not teach the present invention as claimed. Nor does it even suggest it. Sevrain teaches that one provides a prosthetic disc device to provide a cushioning. How can the torque device of Serbousek et al. be substitute for the springs of Sevrain. This would totally destroy the objective of Sevrain to provide a cushioning effect between adjacent vertebra. There is nothing in the combination to teach or event suggest the present invention as claimed.

Once again, the legal arguments previously presented with regard to Beer et al. and Sevrain also apply here.

CONCLUSION

All of the prior art devices teach a prosthetic device to provide cushioning between adjacent vertebra in substitution of removed damaged disc. None of the references teach or even suggest that there is even a need to provide compression to a bone graph positioned between adjacent vertebra in order to assist in the bone grafting process. The advantage of this is not even acknowledged or recognized in the prior art. In addition, the devices shown in the prior art cannot provide the required function and are not designed or constructed to do so.

For all the foregoing reasons, it is believed that the Examiner's rejections should be overturned with regard to claims 1 through 18, and that the Examiner thereby be reversed.

CLAIMS APPENDIX

1. A cervical compression plate assembly having screw receiving elements at opposite ends thereof configured for engaging bone fixation screws extending from respective vertebral elements, means for permitting the distance between said screw receiving elements at opposite ends to be shortened but preventing said distance from increasing; the improvement comprising compression spring means housed in said assembly and configured for continuously urging said screw receiving elements at opposite ends together for thereby providing continuous compressive loading on bone graft material disposed between the vertebral elements.

2. The cervical compression plate assembly of claim 1, including a screw locking mechanism for locking said screws to said plate assembly.

3. The cervical compression plate assembly of claim 2, wherein said screw receiving elements include screw head seats configured for seating the heads of the bone fixation screws at different attitudes.

4. The cervical compression plate assembly of claim 3, wherein said screw locking mechanism includes pressure fit rings in said screw receiving elements for engaging and locking self tapping threaded shanks of said screws in preselected angles of attitude.

5. The cervical compression plate assembly of claim 1, wherein said compression spring means includes a tension spring.

6. The cervical compression plate assembly of claim 5, wherein said tension spring is a wire under tension.

7. The cervical compression plate assembly of claim 6, including a tension torque drive for adjusting the tension applied to said wire.

8. The cervical compression plate assembly of claim 1, wherein said compression spring means includes a compression spring.

9. The cervical compression plate assembly of claim 1, including a removable spacer disposed between said screw receiving elements at opposite ends for initially preventing the distance between said screw receiving elements at opposite ends from being shortened by said compression spring means before application of said plate assembly.

10. A cervical compression plate assembly:

including first and second elongate plates slidably received with respect to each other in their longitudinal direction for adjustably changing the distance between opposite ends of said plate assembly, said opposite ends configured for respective attachment to first and second vertebra

with the aid of bone fixation screws and a lock assembly for locking said first and second plates from further relative distraction therebetween;

and means for permitting the distance between said opposite ends to be shortened;

the improvement comprising:

compression spring means received in said plate assembly and configured for urging said opposite ends together for thereby providing continuous compressive loading.

11. The cervical compression plate assembly of claim 10, including a screw locking mechanism for locking said screws to said plate assembly.

12. The cervical compression plate assembly of claim 11, wherein said screw receiving elements include screw head seats configured for seating the heads of the bone fixation screws at different attitudes.

13. The cervical compression plate assembly of claim 12, wherein said screw locking mechanism includes pressure fit rings in said screw receiving elements for engaging and locking self tapping threaded shanks of said screws in preselected angles of attitude.

14. The cervical compression plate assembly of claim 10, wherein said compression spring means includes a tension spring.

15. The cervical compression plate assembly of claim 14, wherein said tension spring is a wire under tension.

16. The cervical compression plate assembly of claim 15, including a tension torque drive for adjusting the tension applied to said wire.

17. The cervical compression plate assembly of claim 10, wherein said compression spring means includes a compression spring.

18. The cervical compression plate assembly of claim 10, including a removable spacer disposed between said opposite ends for initially preventing the distance between said opposite ends from being shortened by said compression spring means before application of said plate assembly.

EVIDENCE APPENDIX

Not applicable.

RELATED PROCEEDINGS APPENDIX

Not applicable.